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Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (*in triplicate*) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee,

8ECAP

Mark H. Christman
Counsel
Legal D-7158
1007 Market Street
Wilmington, DE 19898
(302) 774-6443

RECEIVED
3/17/95

ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation 's TSCA §8(e) reporting standard[2]. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.[3] Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

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[2]In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment, See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

[3]A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is a appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria *provided that* such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not.exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the Statement of Interpretation follow:

o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should not be regarded as final EPA policy or intent[4], the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).

o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.

othe "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.[5];

othe "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.

othe "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy .

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[4]The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

[5] *See, e.g,* 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

> Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). *See also*, Rollins Environemntal Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the Statement of Interpretation, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

> ...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the Statement of Interpretation. Given the statute and the Statement of Interpretation's explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a substantial risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

> "a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public."

Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, *See*, 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

Attachment

Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy",43 Fed Reg 11110 (3/16/78) and the June 1991 *Section 8(e) Guide.*

TEST TYPE	1978 POLICY CRITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
ACUTE LETHALITY		
Oral	N}	Y}
Dermal	N}	Y}
Inhalation (Vapors)	}[6]	}[7]
aerosol	N}	Y}
dusts/ particles	N}	Y}
SKIN IRRITATION	N	Y[8]
SKIN SENSITIZATION (ANIMALS)	N	Y[9]
EYE IRRITATION	N	Y[10]
SUBCHRONIC (ORAL/DERMAL/INHALATION)	N	Y[11]
REPRODUCTION STUDY	N	Y[12]
DEVELOPMENTAL TOX	Y[13]	Y[14]

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[6] 43 Fed Reg at 11114, comment 14:

"This policy statements directs the reporitng of specifiec effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemicalL unknown effects occurring during such a range test may have to be reported if they are those of concern tot he Agency and if the information meets the criteria set forth in Parts V and VII."

[7] Guide at pp.22, 29-31.

[8] Guide at pp-34-36.

[9] Guide at pp-34-36.

[10] Guide at pp-34-36.

[11] Guide at pp-22; 36-37.

[12] Guide at pp-22

[13] 43 Fed Reg at 11112

"Birth Defects" listed.

[14] Guide at pp-22

NEUROTOXICITY	N	Y[15]
CARCINOGENICITY	Y[16]	Y[17]
MUTAGENICITY		
In Vitro	Y}[18]	Y} [19]
In Vivo	Y}	Y}
ENVIRONMENTAL		
Bioaccumulation	Y}	N
Bioconcentration	Y}[20]	N
Oct/water Part. Coeff.	Y}	N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N
Reprodcutive	N	N

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[15] Guide at pp-23; 33-34.

[16] 43 Fed Reg at 11112
"Cancer" listed

[17] Guide at pp-21.

[18] 43 Fed Reg at 11112; 11115 at Comment 15
"Mutagenicity" listed/ *in vivo* vs *invitro* discussed; discussion of "Ames test".

[19] Guide at pp-23.

[20] 43 Fed Reg at 11112; 11115 at Comment 16.

CAS: 75-63-8
Chem: Bromotrifluoromethane
Title: Exposure to Rats of 80% Freon(r) 13B1 and 20% Oxygen
Date: 2/26/68
Summary of Effects: Unresponsive to sound and head bobbing

ACUTE INHALATION TOXICITY OF BROMOTRIFLUOROMETHANE (FREON® 13B1)

I. Exposure of Rats to Atmospheres of 80% Freon® 13B1 and 20% Oxygen

Medical Research Project No. 876

Haskell Laboratory Report No. 46-68

SUMMARY

A total of 70 rats, in eleven exposures, have been exposed to atmospheres containing 80% Freon® 13B1 and 20% oxygen. With one exception, the exposures were all for four hours. The various samples of Freon® 13B1 were differentially enriched with "high" and "low" boilers to give composite test mixtures representative of those that would result from the extremes of process conditions.

Typically, the test materials caused irregular breathing, head bobbing and unresponsiveness at the test levels. Three deaths occurred.

The sample enriched with "naturally-occurring-impurities" caused the only pathologic effects observed. In one experiment, 2/2 rats sacrificed 14 days after exposure to an atmosphere containing 80% (v/v) of this material had heavier than normal lungs. This effect was not accompanied by any observable histopathologic effect. When this experiment was repeated with ten rats, seven of which were sacrificed 14 days after exposure, 6/7 of the lung weights were within the normal range and the ratios of lung weight to body weight for all seven were within normal limits at the 95% confidence level. However, three rats died during this exposure. Histopathologic evaluation of their tissues revealed only pulmonary hemorrhage and edema. No histopathologic effects attributable to the test material were observed in any of the tissues from the survivors that were examined.

In general, the results of these tests are in agreement with those reported by Paulet (1). They also substantiate our assessment of Freon® 13B1 as a material of low inhalation toxicity. They also indicate that certain fluoroalkanes, which can occur in the manufacture of Freon® 13B1 by our present process, are significantly more toxic than bromotrifluoromethane. Thus current specification levels for impurities in Freon® 13B1 for fire extinguishment use should not be exceeded.

ACUTE INHALATION TOXICITY OF BROMOTRIFLUOROMETHANE (FREON® 13B1)

1. Exposure of Rats to Atmospheres of 80% Freon® 13B1 and 20% Oxygen

Medical Research Project No. 876

Haskell Laboratory Report No. 46-68

INTRODUCTION

Bromotrifluoromethane (Freon® 1301, Freon® 13B1, F-1301, F-13B1) is a candidate fire extinguishing agent in applications where it would function by "flooding" the affected area. Since it is possible that humans could be in the areas "flooded", it was decided to carry out human exposures to the material. As a prelude to these exposures, rats were exposed to an atmosphere of 80% Freon® 13B1/20% oxygen (v/v) for four hours.

MATERIALS

Inhalation exposures with rats were carried out with four different samples of F-13B1. The first sample used was high purity commercial material (H-4363). This was atypical material in that it was purer than could be expected from routine production. Consequently, a second sample was prepared which was enriched with pure "high boilers" (H-4375). This was followed by a third sample (H-4455) enriched with pure "high boilers" and "low boilers" to simulate material more representative of commercial production. These samples were followed by the fourth and last sample (H-4580) which was made by combining aliquots of F-13B1 from various production runs, which were high in one or more impurities, and adding other "pure" impurities. The aliquots of production material used to add the impurities to make H-4580 were selected from runs representing extremes of process conditions so that all possible production impurities would be present. This "naturally" impure sample was subsequently used for human inhalation exposures (2).

The composition of all samples is shown in Table 1.

The test samples were made up in the above way because all of the commercial material available at the start of these studies was either purer than usual or was rich in either "high boilers" or "low boilers" but not both.

PROCEDURES

A. The liquid test material was metered from the inverted cylinder into a copper expansion coil heated at 60°C. The gaseous test material (2.4 L/min.) and gaseous oxygen (0.6 L/min.) were separately metered into a mixing chamber and then into the 16-liter exposure chamber. Six ChR-CD rats of initial body weight 246-310 grams were used per exposure. Each exposure lasted four hours. Oxygen content was checked periodically with a Beckman portable oxygen meter. For each of the test materials, two rats were sacrificed for histopathologic evaluation at each of 1, 2 (3), 7 and 14 days after exposure.

B. The conditions were altered slightly in a special exposure with H-4580. For this four-hour exposure, ten ChR-CD rats of initial body weight 291-314 grams were used instead of six. The flow of H-4580 was 4.0 L/min. and that of oxygen was 1.0 L/min. A control group received comparable flows of nitrogen and oxygen respectively. Survivors were sacrificed for histopathologic evaluation 14 days after exposure.

CLINICAL RESULTS

The clinical signs and mortality ration for the various exposures are shown in Table II. It can be seen that all samples caused head bobbing, unresponsiveness and irregular breathing. In addition, apparent incoordination was seen during exposure to H-4455 and H-4580. Slight salivation and a red discharge around the eyes were each observed during one or two exposures. Recovery took 5-10 minutes after the end of the exposure. Very minor weight losses were frequently seen the first day after exposure.

Head bobbing has been observed previously with, e.g., Freon® 21 at levels of 20,000 ppm and above and with dichloromethane at 15,000 ppm and above (3,4).

PATHOLOGY - EXPOSURE PROCEDURE A

H-4363 &: H-4375 — There were no gross or microscopic effects attributable to the material observed in any of the tissues examined.*

H-4455: — No gross effects attributable to the test material were observed. No histopathologic effects attributable to the compound were observed in any of the tissues examined.*

* Lung, trachea, liver, kidney, brain, spleen, bone marrow, testis, thymus, stomach, and intestine.

PATHOLOGY - PROCEDURE A (Cont'd.)

II-4580: Both rats sacrificed 14 days after exposure had hyperinflated and heavy lungs. Microscopically, no effects attributable to the exposures could be observed in any of the tissues examined.*

PATHOLOGY - PROCEDURE B

It was because of the heavy lungs observed in the above two rats that the exposure described as Procedure B was run. When the survivors were sacrificed 14 days after this latter exposure, one test rat had a lung weight in excess of 2 grams. The ratios of lung weight to body weight were compared between the test and control groups and found to be not significantly different at the 95% confidence level. Microscopically, slight to moderate focal pulmonary edema and hemorrhage were observed in 2/7 of the survivors from the II-4580 exposure. These effects may not be related to the exposures. Severe sloughing of tracheal mucosa was observed in the test rat that had the heavy lungs. Mild sloughing was observed in one test and one control rat.

The test rats that died during exposure to II-4580 by Procedure B showed marked pulmonary congestion and edema upon microscopic examination of these tissues. No other effects attributable to the test material were observed in any of the other tissues examined.*

SUMMARY

A total of 70 rats, in eleven exposures, have been exposed to atmospheres containing 80% Freon® 13B1 and 20% oxygen. With one exception, the exposures were all for four hours. The various samples of Freon® 13B1 were differentially enriched with "high" and "low" boilers to give composite test mixtures representative of those that would result from the extremes of process conditions.

Typically, the test materials caused irregular breathing, head bobbing and unresponsiveness at the test levels. Three deaths occurred.

The sample enriched with "naturally-occurring-impurities" caused the only pathologic effects observed. In one experiment, 2/2 rats sacrificed 14 days after exposure to an atmosphere containing 80% (v/v) of this material had heavier than normal lungs. This effect was not accompanied by any observable histopathologic effect. When this experiment was repeated with ten rats, seven of which were sacrificed 14 days after exposure, 6/7 of the lung weights were within the normal range and the ratios of lung weight to body weight for all seven were within normal limits at the 95% confidence level. However, three rats died during this exposure. Histopathologic evaluation of their tissues revealed only pulmonary hemorrhage and edema. No histopathologic effects attributable to the test material were observed in any of the tissues from the survivors that were examined.

SUMMARY (Cont'd.)

In general, the results of these tests are in agreement with those reported by Paulet (1). They also substantiate our assessment of Freon® 13B1 as a material of low inhalation toxicity. They also indicate that certain fluoroalkanes, which can occur in the manufacture of Freon® 13B1 by our present process, are significantly more toxic than bromotrifluoromethane. Thus current specification levels for impurities in Freon® 13B1 for fire extinguishment use should not be exceeded.

REFERENCES

(1) Paulet, G., Arch. Mal. Prof. 23, 341 (1962).

(2) Haskell Laboratory Report No. 230-66.

(3) Haskell Laboratory Report No. 128-64.

(4) Haskell Laboratory Report No. 134-64.

Report by: Richard S. Waritz
Chief, Inhalation Toxicology Sectio

Approved by: J. Wesley Clayton, Jr.
Assistant Director

RSW/jch
Date: February 26, 1968

Triage of 8(e) Submissions

Date sent to triage: 2/6/96 NON-CAP (CAP)

Submission number: 13157A TSCA Inventory: (Y) N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) SBTOX SEN (w/NEUR)

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

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Notes:

Contractor reviewer : LPS Date: 5/11/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1192 - 13157 SEQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: E. I. Dupont de Nemours and Company

SUB. DATE: 10/18/92 OTS DATE: 11/02/92 CSRAD DATE: 03/17/95

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
0539 REFER TO CHEMICAL SCREENING
0576 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER HISTORIES
0404 LABELS/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME:
Freon 13B1

CAS#
75-63-8

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCCIRCL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE ABORST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0229	METAB/PHARMACO (ANIMAL)	01 02 04
0249	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PRODUSE/PROC	01 02 04
0251	MSDS	01 02 04
0259	OTHER	01 02 04

TRIAGE DATE: NON-CBI INVENTORY
YES
CAS SR NO
IN PLANNING

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REJ-R

SPECIES
Rat

TOXICOLOGICAL CONCERN:
LOW Acute Inhalation Toxicity
MED
HIGH

USE: Fire extinguishment

PRODUCTION:

#13157A
L

Acute inhalation toxicity is of low concern based on low mortality and clinical signs of head bobbing, unresponsiveness and irregular breathing in rats exposed to 4 samples of an 80% freon/20% oxygen mixture for 4 hours. Mortality and corresponding doses were not provided. Mortality of 3/10 was reported in one experiment. Histopathological examination revealed pulmonary hemorrhage and edema. The observation of marked pulmonary congestion and edema in sample H-4580 was also reported.